NOV 0 9 2001

510(k) Summary For N Lp(a) Standard SY

K 013126

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Rebecca S. Ayash Tel: 302-631-6276
Preparation date:	September 14, 2001

2. **Device Name/ Classification:**

N Lp(a) Standard SY:	Calibrator
Classification Number:	Class II (862.1150)

3. **Identification of the Legally Marketed Device:**

Beckman Coulter Lipoprotein(a) Calibrator (LPA CAL), K000121

4. **Device Description:**

N Lp(a) Standard SY is a lyophilized standard prepared from human serum with stabilizers and preservative. It is intended to establish reference curves for the quantitative determination of human lipoprotein(a) [Lp(a)] by immunochemical with BN™ Systems.

5. **Device Intended Use:**

Establishment of reference curves for the immunochemical determination of human lipoprotein(a) [Lp(a)] in serum or plasma with BN™ Systems.

6. **Medical device to which equivalence is claimed and comparison information:**

There are a number of *in vitro* diagnostic products that are used for the establishment of reference curves. One such product is the Beckman Coulter Lipoprotein(a) Calibrator (LPA CAL), K000121. N Lp(a) Standard SY, like the LPA CAL is intended to be used for the calibration of Lp(a) protein by rate nephelometry.

7. **Device Performance Characteristics:**

Stability:
Stability was evaluated according to Dade Behring protocols and the standard was found to be stable for at least 24 months at +2° to +8° C, as originally packaged and for at least 5 days at +2° to +8° C, once reconstituted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 0 9 2001

Ms. Rebecca S. Ayash
Director, Regulatory Affairs
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: k013126
Trade/Device Name: N Lp(a) standard SY
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIS
Dated: September 14, 2001
Received: September 19, 2001

Dear Ms. Ayash:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

K013126

Device Name: N Lp(a) Standard SY

Indications for Use:

Establishment of reference curves for the immunochemical determination of human lipoprotein(a) [Lp(a)] in serum or plasma with BN™ Systems.

R. Chaudhari for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter-Use _____
(Optional Format 1-2-96)